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VERTEX PHARMACEUTICALS INC.
130 WAVERLY STREET
CAMBRIDGE MA 02139-4242

In re Application of :
Michael Hale et al :
Serial No.: 10/626,356 : PETITION DECISION
Filed: July 24, 2003 :
Attorney Docket No.: VPI/00-122 :

This is in response to the petition under 37 CFR 1.181, filed August 30, 2006, requesting withdrawal of the Final rejection.

BACKGROUND

A review of the file history shows that the examiner mailed a Non-Final Rejection to applicants on November 3, 2005, following an earlier Office action requiring restriction between the product (compound) claims and process of using claims with applicants electing the product claims for prosecution, setting forth the following items:

- A. The petition for correction of the inventorship was granted.
- B. The traversal of the restriction requirement was acknowledged and replied to with the requirement being maintained, but subject to rejoinder if the product claims were found allowable. Claims 23 and 27-41 were withdrawn as non-elected method of using claims.
- C. Claim 1 was objected to for some typographical errors and claims 5, 9 and 13 were objected to as substantial duplicate of other claims.
- D. Claims 21-22 were rejected under 35 U.S.C. 112, first paragraph, as lacking enablement in the specification with respect to the term "anti-viral agent".
- E. Claim 18 was rejected under 35 U.S.C. 112, second paragraph as being indefinite as some compounds claimed were outside the scope of claim 1 from which it depended.
- F. Claims 1-9 and 18-22 were rejected for obvious double patenting over SN 10/919,774 and also provisionally rejected under 35 U.S.C. 103(a) over the same application.

Applicants filed an initial response to the above Non-Final Rejection on March 29, 2006, and a compliant amended response on May 16, 2006, by amending claims 1-3, 6-7, 10-11, 18-19 and 21-22, and canceling claims 14-17, 24-26 and 42-43. Each of the rejections and objections were responded to appropriately.

The examiner mailed a Final Office action to applicants on July 25, 2006, withdrawing all of the previous objections and rejections of record. In view of the allowance of the product claims,

method claims 23 and 27-41 were rejoined for prosecution. Claims 23 and 27-41 were then rejected under 35 U.S.C. 112, first paragraph, as lacking enablement with respect to treatment protocols for numerous diseases and conditions. The examiner also stated that applicant's amendments necessitated the new ground of rejection.

Applicants filed this petition on August 30, 2006, objecting to the finality of the Office action as premature.

DISCUSSION

Applicants request withdrawal of the finality of the Office action of July 25, 2006, [citing MPEP §706.07(c)] on the basis that the examiner has introduced a new ground of rejection which was not necessitated by applicants' actions or amendments..

Applicants indicate that they have spoken with the examiner and her supervisor prior to filing this petition in an effort to have the finality withdrawn or understand why finality is considered proper. Applicants were referred to M.P.E.P. 706.07(a) as stating the general policy as to when finality of an Office action is proper. It states as follows:

Under present practice, second or any subsequent actions on the merits shall be final, except where the examiner introduces a new ground of rejection that is neither necessitated by applicant's amendment of the claims nor based on information submitted in an information disclosure statement filed during the period set forth in 37 CFR 1.97(c) with the fee set forth in 37 CFR 1.17(p).

In response applicants cite M.P.E.P. 706.07, as follows (emphasis added):

Before final rejection is in order a clear issue should be developed between the examiner and applicant. To bring the prosecution to as speedy conclusion as possible and at the same time to deal justly by both the applicant and the public, the invention as disclosed and claimed should be thoroughly searched in the first action and the references fully applied; and in reply to this action the applicant should amend with a view to avoiding all the grounds of rejection and objection....

While the rules no longer give to an applicant the right to "amend as often as the examiner presents new references or reasons for rejection," present practice does not sanction hasty and ill-considered final rejections. The applicant who is seeking to define his or her invention in claims that will give him or her the patent protection to which he or she is justly entitled **should receive the cooperation of the examiner to that end, and not be prematurely cut off in the prosecution of his or her application....**

The examiner should never lose sight of the fact that in every case the applicant is entitled to a full and fair hearing, and that a clear issue between applicant and examiner should be developed, if possible, before appeal. However, it is to the interest of the applicants as a class as well as to that of the public that prosecution of an application be confined to as few actions as is consistent with a thorough consideration of its merits....

In making the final rejection, all outstanding grounds of rejection of record should be carefully reviewed, and any such grounds relied on in the final rejection should be reiterated. They must also be clearly developed to such an extent that applicant may readily judge the advisability of an appeal unless a single previous Office action contains a complete statement supporting the rejection.

However, where a single previous Office action contains a complete statement of a ground of rejection, the final rejection may refer to such a statement and also should include a rebuttal of any arguments raised in the applicant's reply. If appeal is taken in such a case, the examiner's answer should contain a complete statement of the examiner's position.

Applicants argue that they have not had a full or fair opportunity to address the rejection of the method claims under 35 U.S.C. 112, first paragraph, for lack of enablement, as it was not applied to the claims examined in the first Office action and rejected under 35 U.S.C. 112, first paragraph, for lack of enablement, since the reasons for lack of enablement are different. Thus a clear issue has not been developed in a manner which would properly support an Appeal to the Board of Patent Appeals and Interferences. Applicants also indicate that under Final rejection procedural options are limited to canceling the rejected claims (as suggested by the examiner, amending the claims (with no guarantee that the amendment would be entered) and filing a Notice of Appeal or filing RCE papers (or filing a Divisional application). Applicants argue that filing of RCE papers wastes both time and money in bringing the prosecution of this application to a close and filing Divisional applications would result in multiple patents and the resulting maintenance fees, etc.

M.P.E.P. 821.04 addresses situations where rejoinder of restricted inventions is appropriate, as here, and states as follows (emphasis added):

The propriety of a restriction requirement should be reconsidered when all the claims directed to the elected invention are in condition for allowance, and the nonelected invention(s) should be considered for rejoinder. Rejoinder involves withdrawal of a restriction requirement between an allowable elected invention and a nonelected invention and examination of the formerly nonelected invention on the merits. In order to be eligible for rejoinder, a claim to a nonelected invention must depend from or otherwise require all the limitations of an allowable claim. A withdrawn claim that does not require all the limitations of an allowable claim will not be rejoined. Furthermore, where restriction was required between a product and a process of making and/or using the product, and the product invention was elected and subsequently found allowable, all claims to a nonelected process invention must depend from or otherwise require all the limitations of an allowable claim for the claims directed to that process invention to be eligible for rejoinder....

Rejoined claims must be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112....

The provisions of MPEP § 706.07 govern the propriety of making an Office action final in rejoinder situations. **If rejoinder occurs after the first Office action on the merits, and if any of the rejoined claims are unpatentable, e.g., if a rejection under 35 U.S.C. 112, first paragraph is made, then the next Office action may be made final** where the new ground of rejection was necessitated by applicant's amendment....

If restriction is required between product and process claims, for example, and all the product claims would be allowable in the first Office action on the merits, upon rejoinder of the process claims, it would not be proper to make the first Office action on the merits final if the rejoined process claim did not comply with the requirements of 35 U.S.C. 112, first paragraph. This is because the rejoinder did not occur after the first Office action on the merits.

The situation presented herein is specifically addressed in the above section of the M.P.E.P. Although none of the rejoined claims were amended and none were previously rejected under 35 U.S.C. 112, second paragraph, or over art, the making of the Office action where claims are rejoined and examined for the first time is permitted. The examiner and her Supervisor have followed the guidelines set forth in the M.P.E.P.

The actions of the examiner are determined to be proper and in accordance with permissible Office practice.

DECISION

The petition is **DENIED.**

The application will be forwarded to the examiner for consideration of the amendment filed October 25, 2006.

Should there be any questions about this decision please contact William R. Dixon, Jr., by letter addressed to Director, TC 1600, at the address listed above, or by telephone at 571-272-0519 or by facsimile sent to the general Office facsimile number 571-273-8300.

A handwritten signature in cursive script, reading "George C. Elliott".

George C. Elliott
Director, Technology Center 1600